

Markush group. Applicant respectfully submits that claims 3, 5-7, 16, 17, and 21 are a proper Markush group. Applicants respectfully address the Examiner's attention to 2173.05(h) I. of the MPEP that states “[o]ne acceptable term of alternative expression, which is commonly referred to as a Markush group, recites members as being “selected from the group consisting of A, B, and C.” This is exactly the form used in claims 3, 5-7, 16, 17, and 21. Accordingly, Applicants respectfully submit that claims 3, 5-7, 16, 17, and 21 are not an improper Markush group.

Claim 7 was rejected for using the term “GLA-3,” which the Examiner alleged is improper. Applicant respectfully submits that one of ordinary skill in the art would readily know that the term “GLA-3” is used for omega 3 gamma-linolenic acid. Applicant, however, has amended claim 7 to recite omega 3 gamma-linolenic acid.

The Examiner further suggested that claim 17 be amended to replace the phrase “to prevent or facilitate the repair of skin” with the phrase “prevent damage of skin or facilitate the repair of skin.” Applicant has amended claim 17 as suggested by the Examiner. Applicant respectfully submits that the objections to claims 3, 5-7, 16, 17, and 21 has been overcome. For the above reasons, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of these claims.

THE REJECTIONS UNDER 35 U.S.C. § 112

Claims 1, 9, 11-13, 19, 21, and 24 were rejected under 35 U.S.C. § 112, second paragraph, for the reasons set forth on pages 2-3 of the Office Action. The Examiner rejected claims 1 and 24 for reciting “a patient having skin.” The Examiner alleges that it is unclear if the claims exclude a particular group of patients. The phrase “a patient having skin” was included in claims 1 and 24 merely to establish antecedent basis for use of the term “skin” later in the claim. Clearly, the claims would exclude patients without skin. Applicant, however, has amended claims 1 and 24 to delete the phrase “a patient having skin.”

Claim 9 was rejected for reciting “red veterinary petrolatum.” Red veterinary petrolatum is the same as petrolatum commonly used in cosmetic formulations. Accordingly, Applicant has amended claim 9 to delete the phrase “red veterinary petrolatum” and to simply recite “petrolatum.”

Claims 11 and 13 were rejected for reciting the phrase “if present.” Applicant notes that claims 11 depends from claim 10. Claim 10, as amended, recites a dermatological

agent further comprising *at least one of a* cysteine component, magnesium component, manganese component, copper component, or selenium component. Accordingly, each component recited in the Markush group of claim 11 is not required, all that is required is one of the components listed in the Markush group. Therefore, claim 11 recites amounts for each of the components “if present.” Similarly, claim 13 recites a dermatological agent further comprising *at least one of* wild yam root, wild yam extract, yellow dock, bupleurum, poria cocos, gentian root, myrrh gum, hawthorn berry extract, marshmallow root, rosemary extract, black cohosh, soy or ginger. Again, each component recited in the Markush group of claim 13 is not required. Therefore, claim 11 recites amounts for each of the components “if present.”

Claims 12 and 13 were rejected for reciting only some components as extracts. In response Applicant has amended claims 12 and 13 to recite that each component is an “extract.” For the above reasons, Applicant respectfully requests that the rejection of claims 1, 9, 11-13, 19, 21, and 24 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

THE DOUBLE PATENTING REJECTION

Claims 1-27 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/501,218. As this is a provisional rejection, Applicants will address the rejection when either copending Application No. 09/3501,218 or the present application is allowed.

THE REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-3 were rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 5,891,440 to Lansky (“Lansky”) for the reasons set forth on page 4 of the Office Action. The Office Action states that Lansky discloses an ointment comprising pomegranate extract and other plant or herbal extracts. The Office Action further states that the composition disclosed in Lansky discloses cocoa butter which is a moisturizing agent. The rejection of claim 3 is rendered moot by the cancellation of that claim. With regard to independent claim 1 and dependent claim 2, Applicant respectfully traverses the rejection.

Lansky teaches an oral phytoestrogen supplement prepared from pomegranate material, *e.g.*, pomegranate seeds, and schizandra berries and Chinese asparagus root (*See e.g.*, Lansky, Column 2, lines 49-56). Lansky also teaches an ointment prepared by pressing pomegranate seed to obtain oil and mixing the oil with coconut milk to form a mixture (*See e.g.*, Lansky, Column 3, lines 7-11). Lansky further discloses that the oral supplement or ointment may be administered to relieve various symptoms in menopausal women or postmenopausal women (*See e.g.*, Lansky, Column 3, lines 50-56).

In contrast, the composition claimed in claim 1, as amended, recites a composition comprising pomegranate extract, a hydrophobic moisturizing agent, *a hydrophilic moisturizing agent*, and *a mono- or poly-hydroxy acid moisturizing agent*. Lansky fails to disclose or even suggest a hydrophilic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin or the mono- or poly-hydroxy acid moisturizing agent in an amount sufficient to exfoliate at least a portion of the patient's skin, as required by independent claim 1. Although, Lansky discloses cocoa butter which is a hydrophobic moisturizer, he fails to disclose or even suggest a hydrophilic moisturizing agent or a mono- or poly-hydroxy acid moisturizing agent. Since anticipation requires that each and every element of a claim must be taught by a single prior art reference, Applicant respectfully submits that Lansky does not anticipate claims 1-3. For the above reasons, Applicant respectfully request that the rejection of claims 1-3 under 35 U.S.C. § 102(a) be reconsidered and withdrawn.

The Examiner also rejected claims 24-27 under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 5,985,300 to Crotty et al. ("Crotty") for the reasons set forth on pages 4-5 of the Office Action. The Office Action states that Crotty discloses skin care compositions containing fruit extracts, zinc salts and other components such as ceramides, vitamins, mono- or poly-hydroxy acids, etc.

Crotty discloses a cosmetic product that is an adhesive strip to remove keratotic plugs and to deliver active ingredients to the skin (*See, e.g.*, Crotty, column 2, lines 40-42). A variety of active ingredients are disclosed.

In contrast, claim 24, as amended, recites a dermatological agent comprising at least one fruit extract in an amount sufficient to neutralize free radicals; a transition metal component in an amount sufficient to inhibit or reduce inflammation; a hydrophobic

moisturizing agent, *a hydrophilic moisturizing agent*, a mono- or poly-hydroxy acid moisturizing agent, and a pharmaceutically acceptable carrier. There is absolutely no disclosure, or even a suggestion, in Crotty of a composition that includes all three of the types of moisturizing agents disclosed in independent claim 24, as amended. Although Crotty discloses alpha- and beta-hydroxycarboxylic acids and ceramides (which are a hydrophobic moisturizer), there is absolutely no disclosure or suggestion of a hydrophilic moisturizer as required by claim 24, as amended. Since anticipation requires that each and every element of a claim must be taught by a single prior art reference, Applicant respectfully submits that Lansky does not anticipate claims 24-27. For the above reasons, Applicant respectfully request that the rejection of claims 24-27 under 35 U.S.C. § 102(a) be reconsidered and withdrawn.

The Examiner also rejected claims 1-3, 5, 6, 10, 11, and 14-27 under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 6,030,622 to Shehadeh ("Shehadeh") for the reasons set forth on page 5 of the Office Action. The Office Action states that Shehadeh discloses a herbal extract composition containing pomegranate extract, minerals such as zinc, magnesium, copper, proteins, vitamins, and other plant extracts such as echinacea for immunity boosting. The Office Action also states that the vitamin E of Shehadeh reads on the moisturizing agent and that proteins reads on the hydrophilic moisturizing agent. Applicant respectfully traverses the rejection.

Shehadeh discloses an herbal extract composition including arum, pomegranate, tea, and hibiscus, and various combinations thereof (*See e.g.*, Shehadeh, Column 5, lines 58-64), and teaches that this composition is a useful potential source or candidate for immunity boosting therapies and treatments for humans and animals suffering from disorders, diseases, infections, or conditions such as leukemia, renal failure, various cancers and tumors, viral infections, bacterial infections and parasitic infections (*See e.g.*, Shehadeh, Column 15, lines 22-29).

In contrast, the composition claimed in claim 1, as amended, recites a composition comprising pomegranate extract, *a hydrophobic moisturizing agent*, *a hydrophilic moisturizing agent*, and *a mono- or poly-hydroxy acid moisturizing agent*. Shehadeh fails to disclose or even suggest a mono- or poly-hydroxy acid moisturizing agent in an amount sufficient to exfoliate at least a portion of the patient's skin, as recited in claim

1, as amended. Furthermore, Shehadeh fails to disclose or even suggest a hydrophobic moisturizing agent or a hydrophilic moisturizing agent. The Examiner alleges that vitamin E and proteins reads on the recited moisturizing agents. The Examiner, however, provides no evidence that the vitamin E or the proteins disclosed in Shehadeh are moisturizing agents and Shehadeh is completely silent as to moisturizing agents. In particular, Applicant notes that only some proteins, such as laurdimonium hydroxypropyl hydrolyzed wheat protein and hair keratin amino acids, are moisturizing agents (*See, e.g.*, Specification, page 15, lines 6-9). Not all proteins are moisturizing agents. Since anticipation requires that each and every element of a claim must be taught by a single prior art reference, Applicant respectfully submits that Lansky does not anticipate claims 1-3, 5, 6, 10, 11, and 14-27. For the above reasons, Applicant respectfully request that the rejection of claims 1-3, 5, 6, 10, 11, and 14-27 as under 35 U.S.C. § 102 (a) be reconsidered and withdrawn.

THE REJECTIONS UNDER 35 U.S.C. § 103

The Examiner rejected claims 1-27 as being obvious over Crotty in view of Lansky or Crotty and Lansky in view of U.S. Patent No. 6,030,620 to Pillai (“Pillai”) for the reasons set forth on pages 5-7 of the Office Action. Applicant respectfully traverses the rejection.

Pillai discloses a skin care composition comprising an extract of chick peas in an amount to provide an estrogenic activity equivalent to at least 1nM of estradiol and a cosmetically acceptable vehicle (*See, e.g.*, Pillai, column 2, lines 42-48).

As discussed above, Crotty fails to disclose or suggest a composition that includes all three of the types of moisturizing agents, *i.e.*, a hydrophobic moisturizing agent, a hydrophilic moisturizing agent, and a mono- or poly-hydroxy acid moisturizing agent, required by independent claims 1 and 24, as amended. Although Crotty discloses alpha- and beta-hydroxycarboxylic acids and ceramides (which are a hydrophobic moisturizer), there is absolutely no disclosure or suggestion of a hydrophilic moisturizer. The Examiner, however, further alleges that the fruit extracts, plant extracts, phytoestrogens, herbal extracts, alpha- and beta-hydroxycarboxylic acids, anti-inflammatories, vitamins, and flavanoids disclosed in Crotty all read on the claimed moisturizers. Applicant respectfully disagrees. There is absolutely no disclosure or suggestion in Crotty that these components are moisturizers.

Furthermore, the Examiner has provided no evidence at all to support his contention that these components are moisturizers.

Lansky fails to remedy the deficiency in Crotty. As discussed above, Lansky discloses cocoa butter, which is a hydrophobic moisturizer, but fails to disclose or even suggest a hydrophobic moisturizing agent or a mono- or poly-hydroxy acid moisturizing agent. Thus, even if Crotty and Lansky were combined it would not result in the present invention since the combination would not result in a dermatological composition that comprises all three of a hydrophobic moisturizing agent, hydrophilic moisturizing agent, and a mono- or poly-hydroxy acid moisturizing agent. Applicant, however, has unexpectedly discovered that the combination of all three types of moisturizing agent is preferable to any of the moisturizing agents used individually. The combination of all three advantageously moisturizes the skin by exfoliating the skin so that the skin is better able to absorb moisture from the atmosphere (the mono- or poly-hydroxy acid moisturizing agent), inhibiting or preventing the loss of water from the skin (the hydrophobic agent), and by absorbing moisture from the atmosphere to hydrate or facilitate hydration of the skin (the hydrophilic agent) (*See, e.g.*, Specification, page 14, lines 21-25; page 15, lines 1-2; page 15, lines 10-12). Moisturizing the skin advantageously minimizes or prevents the skin from cracking which is important since cracked skin is more susceptible to environmental factors that generate free radicals which damage the skin (*See, e.g.*, Specification, lines 2-6). There is absolutely no disclosure or suggestion in either Crotty or Lansky to use all three moisturizers or the unexpected benefits thereof.

Pillai also does not remedy the deficiencies in Crotty or Lansky. Although, Pillai discloses that his composition may include emollients, some of which are moisturizing agents there is absolutely no disclosure of a mono- or poly-hydroxy acid moisturizing agent. Moreover, there is no motivation to combine these individual references. At best a person of ordinary skill in the art might substitute the moisturizer disclosed in one reference for the moisturizer disclosed in another reference. There is, however, no disclosure or suggestion, to combine all three moisturizers in a dermatological agent. As noted above, Applicant has discovered that by combining all three, each of which moisturizes the skin by a different mechanism, provides an enhanced moisturizing effect. There is absolutely no suggestion in the references to combine the three types of moisturizing agents, as required by the claimed

compositions, or the unexpected advantages of combining all three moisturizing agents. Applicant respectfully submits that this is a classic case of hindsight reconstruction of the prior art utilizing the Applicant's specification and claims as a framework for the Examiner's selection of references when there is no suggestion to combine the references. Applicant respectfully submits that the combination of Crotty and Lansky or Crotty, Lansky, and Pillai do not render claims 1-27 obvious. For the above reasons, Applicant respectfully requests that the rejection under 35 U.S.C. 103(a) be reconsidered and withdrawn.

With regard to all claims not specifically mentioned, these are believed to be allowable not only in view of their dependency on their respective base claims and any intervening claims, but also for the totality of features recited therein.

All claims are believed to be in condition for allowance. Should the Examiner disagree, Applicant respectfully invites the Examiner to contact the undersigned attorneys for Applicant to arrange for an in-person interview in an effort to expedite the prosecution of this matter.

No fee is believed to be due for the amendments herein. Should any fee be required, please charge such fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Paul E. Dietze (45,627)
for *Victor N. Balancia*
Paul E. Dietze (Reg. No. 45,627)
for Victor N. Balancia (Reg. No. 31,231)

Date August 20, 2001

PENNIE & EDMONDS LLP
1667 K Street, N.W.
Washington, DC 20006
(202) 496-4400

Enclosure

APPENDIX A
MARKED UP VERSIONS OF THE AMENDED CLAIMS

1. (Amended) A dermatological agent for managing a dermatological condition in a patient [having skin] comprising:

at least one fruit extract from pomegranate in an amount sufficient to neutralize free radicals;

[at least one] a hydrophobic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;

a hydrophilic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;

a mono- or poly-hydroxy acid moisturizing agent in an amount sufficient to exfoliate at least a portion of the patient's skin; and

a pharmaceutically acceptable carrier.

7. (Amended) The dermatological agent of claim 1, wherein the moisturizing agent is selected from the group consisting of primrose oil, [GLA 3] omega 3 gamma-linolenic acid, flax seed oil, and mixtures thereof.

9. (Amended) The dermatological agent of claim 8, wherein the sunscreen or sunblock component is selected from the group consisting of titanium dioxide, zinc oxide, talc, [red veterinary] petrolatum, a cinnamate, a benzone, a salicylate, a benzoic acid, a benzophenone, and mixtures thereof.

10. (Amended) The dermatological agent of claim 1, further comprising at least one of a cysteine component, magnesium component, manganese component, copper component, or selenium component.

12. (Amended) The dermatological agent of claim 1, further comprising at least one of wild yam root extract, wild yam extract, yellow dock extract, bupleurum extract, poria cocos extract, gentian root extract, myrrh gum extract, hawthorn berry extract,

marshmallow root extract, rosemary extract, black cohosh extract, soy extract or ginger extract.

13. (Amended) The dermatological agent of claim 12, wherein the amount of wild yam root extract, wild yam extract, marshmallow root extract, hawthorn berry extract, and rosemary extract, if present, is from about 0.5 to 8 weight percent each, the amount of yellow dock extract, if present, is from about 1 to 30 weight percent, and the amount of bupleurum extract, poria cocos extract, gentian root and myrrh gum extract, if present, is from about 1 to 20 weight percent each.

17. (Amended) The dermatological agent of claim 1, which further comprises at least one immunity boosting component in an amount sufficient to stimulate the patient's immune system response to prevent [or facilitate repair of damaged] damage of skin or facilitate the repair of skin.

24. (Amended) A dermatological agent for managing a dermatological condition in a patient [having skin] comprising:

at least one fruit extract in an amount sufficient to neutralize free radicals;
a transition metal component in an amount sufficient to inhibit or reduce inflammation;

a hydrophobic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;

a hydrophilic moisturizing agent in an amount sufficient to facilitate hydration of the patient's skin;

a mono- or poly-hydroxy acid moisturizing agent in an amount sufficient to exfoliate at least a portion of the patient's skin; and

a pharmaceutically acceptable carrier.